IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

AMERITOX, LTD., and
MARSHFIELD CLINIC, INC.,

Plaintiffs,

v.

MILLENNIUM HEALTH, LLC,

Defendant.

OPINION AND ORDER

13-cv-832-wmc

In its summary judgment decision, the court denied judgment to defendant Millennium Health, LLC on its claim that the '680 patent is invalid under 35 U.S.C. § 101. Because there was no cross-motion on this claim, the court stopped short of *granting* summary judgment under § 101 to plaintiffs. Having now had the opportunity to consider all of the relevant prior art references as presented to the jury at trial as part of Millennium's § 102 and § 103 defenses, as well as to consider the record in this case as a whole, the court finds that Millennium has failed to demonstrate through clear and convincing evidence that the patent is invalid under § 101. The court will, therefore, enter partial judgment in favor of plaintiffs on defendant Millennium's § 101 defense.

The court considered a number of prior art references in detail in its summary judgment opinion, including most prominently the George Article.[1] (Tr. Ex. 533.) That discussion and the court's reasons for rejecting Millennium's § 101 claim as to the '680 patent will not be repeated, but are incorporated here. (2/19/15 Op. & Order (dkt. #215) 28-56.) Only three references were put to the jury that the court did not have before it on summary judgment: (1) the Preston Article (Tr. Ex. 888); (2) the Kell Patent

[1] S. George and R.A. Braithwaite, *A Pilot Study to Determine the Usefulness of the Urinary Excretion of Methadone and its Primary Metabolite (EDDP) as Potential Markers of Compliance in Methadone Detoxification Programs*, J. Anal. Toxicol. 23(2): 81-85 (1999).

(Tr. Ex. 887); and (3) the Carrieri Article (Tr. Ex. 567). The first and second references were addressed at length during trial, while the jury found as a matter of fact that the Preston Article was not publicly accessible to persons interested in the field of invention before the filing date. (Jury Verdict - Liability (dkt. #414) No. 1.) Therefore, Preston is not prior art, much less "well-known" prior art for purposes of § 101.[2]

As for the Kell Patent, it failed to teach creatinine correction. Instead, the claims were directed towards the use of specific gravity for hydration normalization. This is not proof of conventional teaching of the combination of the elements in the '680 patent using creatinine normalization to account for drug compliance. Even Dr. Wu acknowledged at trial that he was not using creatinine correction for drug compliance purposes as of 2003. Moreover, the closest prior art reference to the claimed invention in this case remains the George Article, which states:

- "there is too large of an interindividual variation to use urinary excretion concentrations of methadone or EDDP as markers of compliance";
- urinary excretion testing "would point to a lack of suitability of using urine concentrations of EDDP or methadone as markers of compliance"; and
- "the only reliable method available to monitor methadone compliance is the use of plasma methadone drug testing."

(Ex. 533.) Because George and at least one other piece of prior art (the Haddow Article) taught away from the claimed combination, the jury likely found the patent was not obvious on that basis.[3] So, too, does this court for patent eligibility purposes. Because

[2] Even if the Preston reference were available for § 101 purposes, the fact that it may have been publicly accessible for §§ 102 and 103 purposes would not make it, a day before the applicable filing date, "well-known art" for patent eligibility purposes under § 101.

[3] The Haddow Article was cited in the specification and formed part of the prosecution history. While acknowledging that the use of "creatinine measurements to reflect hydration" was known,

these articles steer away from the claimed invention, the court is unable to find clear and convincing evidence that the scientific community would have thought to combine the creatinine-normalization step (step (e)) and the comparative step (step (f)). *Cf. In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 764 (Fed. Cir. 2014)

In fairness, the Carrieri Article had noted the correlation between specific gravity and creatinine to adjust for concentration-dilution variation in spot urine samples in a setting outside compliance drug monitoring.[4] (Ex. 567.) Moreover, undisputed expert testimony at trial, as well as examples of use in other settings, including studies of variations in drug metabolite concentrations of a single individual over time, establishes creatinine as a known method for hydration normalization, albeit not for comparison to a population of drug users. Still, as noted above and at summary judgment, problems with the use of creatinine had been recognized in the prior art, which may have steered the scientific community away from its use over specific gravity, at least in the drug testing context. Tellingly, Millennium did not provide *clear and convincing* evidence at trial to controvert this teaching away.

Finally, although Millennium's counsel argued the point, defendant failed to offer clear and convincing evidence, in the form of expert testimony or otherwise, supporting a finding that the use of creatinine normalization in the context of the '680 patent was

---

it teaches that use of creatinine adds "complexity and cost when such measurements are applied in routine and clinical practice," which is why specific gravity was used instead of creatinine for urine samples in children with asthma. (Ex. 566.) Haddow, J., *et al.*, *Replacing Creatinine Measurements with Specific Gravity Values to Adjust Urine Cotinine Concentrations*, Clinical Chem. 562-64 (1994).

[4] Carrieri, *Adjustments to Concentration-Dilution of Spot Urine Samples: Correlation Between Specific Gravity and Creatinine*, Int'l Archives of Occup. & Env't Health 74:63-67 (2001).

preemptive. For example, there was nothing in Dr. Wu's or Dr. Bertholf's reports that established preemption. Indeed, at trial, Millennium made no effort to dispute that drug compliance could be assessed by the more expensive and cumbersome alternative of drawing blood, despite the court relying on that evidence on summary judgment. (2/19/15 Op. & Order (dkt. #215) 55-56.) If anything, evidence proffered by Ameritox at trial of its prior use of specific gravity for equalization of hydration under the Kell patent, reinforced the opposite conclusion.

While declining to invalidate the '680 patent on § 101 grounds, the court would be remiss not to note its own skepticism as to the value of the "advance" embodied in the '680 patent, and even more in the invalidated '895 patent, both as a matter of accepted science and as a marketing tool, a skepticism bolstered by the evidence at trial. Indeed, the uncontroverted evidence at trial suggests the real value of either parties' competing products lay in the collecting of large, proprietary data sets and then differentiating that data by a myriad of characteristics, including age, sex, weight, height, exercise, diet, and prescribed drug dose, to name a few. As set forth in the court's summary judgment decision, this concern was substantially greater with respect to the '895 patent, but remains with respect to the '680 patent as well.[5]

Given the reinvigoration of § 101 by *Alice Corporation v. SLC Bank International,* 134 S. Ct. 2347, 2354 (2014), which was already discussed at length in the court's summary judgment decision, and the fact that the medical field is on the cutting edge of what will hopefully be an explosion of new advances in medical treatments based on the

[5] Unlike element (e) of the claims in the '680 patent, the '895 patent makes the creatinine normalization step effectively redundant because it seeks to patent all biological resting samples -- not just urine and forecloses further invention. (2/19/15 Op. & Order (dkt. #215) 55-56.)

effective mining of "big data" and disciplined use of the scientific method,[6] a real question exists as to the wisdom of continuing to grant patents that last for 20 years on identification of an individual characteristic that may be useful for diagnosis or advances in understanding illnesses.

The facts of this case are illustrative of this problem, since it involves the normalization of a single characteristic in samples from a population for comparison purposes against an individual patient's sample, which is accomplished by use of an already well-known technique -- here, the use of creatinine to account for variations in urine test results due to differences in hydration -- albeit not yet used specifically for comparison of a patient's individual urine sample against a population of other users of that drug at the time of the patent application. Indeed, as disclosed at trial, the application for the '680 patent was filed just as a wave of opioid use in pain management was beginning to build. Naturally following close behind, came a wave of demand by medical professionals to monitor for what Ameritox's former Chief Medical Officer described as "abuse, misuse and diversion" of those powerful drugs. Hence, for better or for worse, a reinvigorated market for drug testing followed.[7]

Given these pressures, it is perhaps unsurprising, if a bit unseemly, that two fierce competitors in this burgeoning and highly profitable market should continue to fight over

---

[6] *See, e.g.*, Nilay D. Shah & Jyotishman Pathak, *Why Health Care May Finally Be Ready for Big Data*, Harv. Bus. Rev. (Dec. 3, 2014), *available at* https://hbr.org/2014/12/why-health-care-may-finally-be-ready-for-big-data; *The Potential Impact of Big Data on Medicine*, N.P.R. (Jan. 25, 2015), http://www.npr.org/2015/01/25/379756156/the-potential-impact-of-big-data-on-medicine.

[7] *See* Christopher Weaver & Anna Wilde Mathews, *Doctors Cash In on Drug Tests for Seniors*, Wall St. J., Nov. 10, 2014, *available at* http://www.wsj.com/articles/doctors-cash-in-on-drug-tests-for-seniors-and-medicare-pays-the-bill-1415676782.

various marketing claims and patents across various courts and the PTO, but it may not be good public policy. However, that question may ultimately be for Congress to determine, not the courts at all, and certainly not for a lone district judge.

Regardless, there is enough in the combination of the elements in the '680 patent to get it over the patent eligibility threshold under current law, particularly in light of the jury upholding the patent on § 102 and § 103 grounds. *See Alice Corp.*, 134 S. Ct. at 2354 (expressing a concern that its rearticulation of the § 101 claim not "swallow all of patent law"). At minimum, defendant Millennium did not meet its burden of providing clear and convincing evidence to the contrary.

ORDER

IT IS ORDERED that partial judgment is AWARDED in plaintiffs' favor with respect to defendant's claim that U.S. Patent No. 7,585,680 is invalid under 35 U.S.C. § 101.

Entered this 24th day of April, 2015.

BY THE COURT:

/s/

_____
WILLIAM M. CONLEY
District Judge